

EXHIBIT C



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Premarket Approval (PMA)



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Note: This medical device record is a PMA supplement. A supplement may have changed the device description/function or indication from that approved in the original PMA. Be sure to look at the [original PMA](#)²³ record for more information.

Device	CLOSER PERCUTANEOUS VASCULAR SURGERY DEVICE
Applicant	ABBOTT VASCULAR INC. 400 Saginaw Drive Redwood City, CA 94063
PMA Number	P960043
Supplement Number	S019
Date Received	05/03/1999
Decision Date	11/22/1999
Advisory Committee	Cardiovascular
Supplement Type	Normal 180 Day Track
Supplement Reason	Change Design/Components/Specifications/Material
Expedited Review Granted?	No
Combination Product	No

Approval Order Statement

Approval for the Closer(TM) PVS Device and the following accessories: the Perclose Mini Knot Pusher, Perclose Snared Knot Pusher and the Clincher(TM) Knot Tying Device. The device is indicated for the percutaneous delivery of suture for closing the common femoral artery access site of patients who have undergone diagnostic catheterization procedures using 5 to 6 Fr. sheaths. The Closer(TM) 6 Fr. PVS System reduces the times to hemostasis, ambulation (5 meters or 16 feet) and discharge in patients who have undergone diagnostic catheterization procedures without complicating clinical conditions (refer to Precautions, Special Patient Populations in the device labeling).

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